NOV - 3 2004

## Section 2 Summary and Certification

### 510(k) Summary of Safety and Effectiveness

Date:

September 24, 2004

Submitter:

GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:

Andrew Kluessendorf
Sr. Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: (414) 362-3063
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Device: Trade Name:

Aware™ Transport Monitor System (includes Aware POD and Aware Transport Monitor)

Common/Usual Name:

Physiological Patient Monitor (Multi-parameter Module)

Classification Names:

Physiological Patient Monitor

Predicate Devices:

K011000 TRAM 2001 Module

Device Description:

The Aware™ Transport Monitor System is a complete, high-acuity patient monitoring system composed of two main parts: the Aware POD and Aware Transport Monitor.

The Aware™ Patient Observation Device (POD) is an acquisition module that measures and processes a patient's physiological parameters. Physiological parameter data acquired by the Aware POD includes 12 Lead ECG, respiration, up to four invasive blood pressure channels (as options), non-invasive blood pressure, Masimo SpO2, dual temperature and cardiac output (optional).

The Aware™ Transport Monitor is designed to be lightweight, rugged, and provide continuous monitoring capability when coupled with a compatible acquisition module. The Aware Transport Monitor is designed to facilitate quick, simple connection of either the Aware POD or TRAM 2001 module (K011000). The Aware Transport Monitor provides a means to alert the clinician of limit violations via audible and visual alarms.

Intended Use:

The Aware™ Transport Monitor System (includes Aware POD and Aware Transport Monitor) is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional medical facility, such as a hospital, clinic, surgical center or doctor's office. It can be used in multiple areas such as operating room (OR), post anesthesia care unit (PACU), emergency department (ED), critical care, surgical intensive care, respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care.

The Aware POD is intended to provide uninterrupted acquisition of physiologic parameter data on adult, pediatric and neonatal patients during non-transport/bedside and transport patient care episodes. Physiological parameter data acquired by the Aware POD includes ECG, invasive blood pressure, non-invasive blood pressure, pulse oximetry, temperature, and respiration. This device acquires, processes and stores information for all aforementioned parameters and transmits this information to a transport or bedside central processing unit for viewing and alarm surveillance purposes.

The Aware Transport Monitor is intended for use as part of a transport monitoring system for intra-healthcare facility transport. When used with the Aware POD or the TRAM acquisition module, this device is intended to provide uninterrupted monitoring of physiologic parameter data for adult, pediatric, and neonatal patients during transport from one area of the healthcare facility to another. Physiological parameter data includes ECG, invasive blood pressure, non-invasive blood pressure, pulse oximetry, temperature, and respiration. Both the Aware POD and TRAM acquisition module acquire, process and store information for all aforementioned parameters.

Technology:

The Aware Transport Monitor System employs the same functional scientific technology as its predicate devices.

Test Summary:

The Aware Transport Monitor System complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures are applied to the development of the Aware Transport Monitor System:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Clinical Use Validation
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion:

The results of these measurements demonstrated that the Aware Transport Monitor System is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2004

GE Medical Systems Information Technologies
c/o Mr. Andrew Kluessendorf
Sr. Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K042642
Trade Name: Aware ™ Transport Monitor System (includes Aware POD and Aware Transport Monitor)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Regulatory Class: II (two)
Product Code: MHX
Dated: September 24, 2004
Received: September 27, 2004

Dear Mr. Kluessendorf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042642

# Indications for Use

510(k) Number (if known): _____

Device Name: Aware™ Transport Monitor System (includes Aware POD and Aware Transport Monitor)

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042642